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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/627,165	07/27/2000	Jongbae Kim	24170	9845

20529 7590 12/18/2003

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 12/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/627,165	KIM ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29 and 31-48* is/are pending in the application.

4a) Of the above claim(s) *1-28 and 35-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29 and 31-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-29 and 31-48 are pending.

Applicants' amendment filed on October 3, 2003 is acknowledged, and applicants' response has been fully considered. Claim 30 have been cancelled, and claims 29, 31 and 33 have been amended. Claims1-28 and 35-48 are non-elected inventions, thus withdrawn from consideration. Therefore, claims 29 and 31-34 are examined.

Election/Restrictions

2. Applicant's election with traverse of Group V, claims 39-34, was made during a telephone conversation between Examiner Hope Robinson and Sheldon McGee on May 10, 2002. The traversal is on the ground(s) that regardless of any differences existing between the inventions of Groups II-V, IX and X, a complete and through search for the invention set forth in any one of the groups would require searching the art areas appropriate to other groups, all of Groups II-V, IX and X fall under class 530, subclass 396, and all of Groups VI-X fall under class 530, subclass 350; several of the inventive groups identified by the Examiner are related by bridging claims generic to the claims within each group, e.g., Group IV (claims 23-28), drawn to a method of enhancing immunity is sub-generic to the elected Group V (claims 29-34), drawn to a method of effectuating antitumor activity, thus, there will not be a serious burden for examiner to search all the claims (pages 12-14 of the response). This is not found persuasive because although the claims of different groups are classified to the same class/subclass, they are directed to different proteins (e.g., Korean Mistletoe lectin of Group II, and Korean Mistletoe Heparin Binding Protein of Group VII), which have different functions and produce different effects, and to different methods (e.g., preparing a lectin from Korean Mistletoe of Group III, enhancing

immunity of Group IV, and effectuating antitumor activity of Group V), which have different method steps and produce different outcome as indicated at pages 4-6 of the previous Office Action. Restriction is proper when two or more claimed inventions are either independent **or** distinct. See MPEP 803. Furthermore, coexamination of each of additional groups would have required a search of additional classes and art areas. For example, if Group III were included, it would require additional searches for class 530, subclass 387.1, and affinity chromatography, if Group IV were included, it would require additional searches in the area of immunity. Thus, coexamination of each of these inventions would require a serious additional burden of search. The restriction groups have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the invention is not coextensive particularly with regard to the literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or make obvious any of the other group. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exist. The requirement is still deemed proper and is therefore made FINAL.

Objection Withdrawn

3. The previous objection of the specification is withdrawn in view of applicants' amendment to the specification and applicant's response at pages 15-16 in the amendment filed October 3, 2003.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

4. The previous rejection of claim 30 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in view of applicants' cancellation of the claim in the amendment filed October 3, 2003.

Claim Rejections - 35 USC § 102

5. The previous rejection of claim 30, 31 and 33 under 35 U.S.C. 102(b) as being anticipated by Yoon *et al.* (International J. Immunopharmacology 20, 163-172 (April-May 1998)), is withdrawn in view of applicants' cancellation of the claim, applicants' amendment to the claim, and applicants' response at pages 17-18 in the amendment filed October 3, 2003.

Claim Rejections - 35 USC § 103

6. The previous rejection of claim 30, 31 and 33 under 35 U.S.C. 103(a) as being unpatentable over Khwaja *et al.* (Proc. Am. Assoc. Cancer Res. Annu. Meet. 28, 303 (1987)) taken with Khwaja (U. S. Patent 5,565,200), is withdrawn in view of applicants' cancellation of the claims, applicants' amendment to the claim, and applicants' response at pages 18-21 in the amendment filed October 3, 2003.

Objections

7. Claims 31 and 33 are objected to because of the use of "SEQ. ID NO.". Use of "SEQ ID NO:" is suggested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 29 and 31-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 29 and 31-34 are indefinite because the claims lack an essential step in the method of effectuating antitumor activity in animals. The omitted step is the outcome for the treatment. Claims 31-34 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

In response, applicants indicate claim 29 has been amended to state "an effective amount" and to state the treatment outcome described in the specification. The response has been considered, however, the argument is not fully persuasive because the term "wherein said effectuating antitumoral activity comprises:.....inhibiting metastasis of a tumor" indicates the definition of the term, it does not indicate the outcome of the treatment. Use of the term "an amount of a lectin isolated from Korean mistletoes effective to enhance an antitumor immune response.....or inhibit metastasis of a tumor".

10. Claims 29 and 31-34 are indefinite because of the use of the term "and/or". The term "and/or" renders the claim indefinite, it is unclear whether the limitation after "and/or" is included or not, and if included is to be read as an alternative "or" or the conjunctive "and".

Claims 31-34 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim 29 is rejected under 35 U.S.C. 102(b) as being anticipated by Yoon *et al.* (International J. Immunopharmacology 20, 163-172 (April-May 1998)).

Yoon *et al.* teach an extract (KM-110) prepared from Viscum album coloratum (Korean mistletoe) inhibits tumor metastasis in experimental lung metastasis of B16-BL6 melanoma or colon 26-M3.1 carcinoma cells (Table 1), and spleen metastasis of L5178Y-ML25 lymphoma cells (Table 2) when administered of KM-110 (100 μg) to mice before tumor inoculation (pages 166-167; claim 29). Claim 29 is anticipated by the reference because the extract of KM-110 prepared from Korean mistletoe contains isolated lectins as shown in the specification and has antitumor activity, and claim 29 recites the lectin of KML-IIU or KML-IIL, but, no characteristic or property of the protein is indicated, thus any lectin having antitumor activity and isolated from Korean mistletoe is considered as KML-IIU or KML-IIL.

In response, applicants indicate Yoon *et al.* teach the use of KM-110, and claims 29-34 are directed to KML-IIU and KML-IIL; the specification shows KML-IIU and KML-IIL are not the same as KM-110, and Yoon's disclosure of KM-110 is not tantamount to a disclosure of isolated KML-IIU and KML-IIL (pages 17-18 of the response). Applicant's response has been

considered, however, the argument is not fully persuasive because the claim recites using an isolated lectin of KML-IIU or KML-IIL in the treatment of tumor, where the sequence, the characteristic or the property of the protein is not indicated, and the specification teaches KM-110 contains KML-IIU or KML-IIL, thus KM-110 prepared from Korean mistletoe and having antitumor activity as indicated by Yoon *et al.* anticipates the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Khwaja *et al.* (Proc. Am. Assoc. Cancer Res. Annu. Meet. 28, 303 (1987)) taken with Khwaja (U. S. Patent 5,565,200).

Khwaja *et al.* teach a lectin, which is isolated from the aqueous extract of Viscum album, Coloratum (Korean mistletoe) by precipitation with 70% ammonium sulfate, absorbing on

Sepharose 4B column, and eluting with 0.15 M lactose in 0.5 M NaCl, has antiocancer activity against the growth of leukemia L1210 cells in culture with IC_{50} of 0.66 ng/ml, and the SDS gel electrophoresis of lectin shows two major bands 29 and 36 kDa (whole abstract). However, Khwaja *et al.* do not disclose the administration of the lectin to an animal. Khwaja teaches aqueous extracts from Korean mistletoe, which contain lectins, viscotoxins and alkaloidal compounds, exhibit antileukemia activity against L1210 cells and anticancer activity in animals bearing tumor cells (column 11, line 57-column 12, line 35; Example 1; claim 12 of the 200' patent). At the time of invention was made, it would have been obvious to one of ordinary skill in the art to use the isolated lectin taught by Khwaja *et al.* in treating an animal having cancer because the use of an active ingredient in the extract would provide an alternative method for effective treatment of cancer. Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made. Claim 29 recites the lectin of KML-IIU or KML-IIL, but, no characteristic or property of the protein is indicated, thus any lectin having antitumor activity and isolated from Korean mistletoe is considered as KML-IIU or KML-IIL.

In response, applicants indicate KML-IIU and KML-IIL are lectins having specific sequences and properties which are clearly distinguishable from the Khwaja *et al.* or the Khwaja patent; neither Khwaja *et al.* nor the Khwaja patent teach or suggest isolated KML-IIU or KML-IIL, and there is no motivation to modify the teachings of either cited reference to produce the inventive subjective matter (pages 18-21 of the response). Applicant's response has been considered, however, the argument is not fully persuasive because the sequences and properties of KML-IIU and KML-IIL are not cited in the claim, thus the lectin of KML-IIU or KML-IIL is

not distinguishable from the lectin of Khwaja *et al.* Since the isolated lectin of Khwaja *et al.* has similar antitumor activity as the Korean mistletoe extract of Khwaja patent, which is used for in vivo treatment, it is obvious to use the isolated active ingredient from the extract as the alternative method for in vivo treatment.

Conclusion

10. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

December 12, 2003

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